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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,689	04/14/2004	Arthur D. Ballard	60305-USA	8065
7590	03/15/2006			
Paul A. Fair Patent Administration FMC Corporation 1735 Market street Philadelphia, PA 19103				
EXAMINER RAZA, SAIRA B				
ART UNIT		PAPER NUMBER		
1711				
DATE MAILED: 03/15/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/824,689	Applicant(s) BALLARD ET AL.	
	Examiner Saira Raza	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 20,40,43,46 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19,21-39,41,42,44,45 and 47-52 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/04, 8/05, 11/05</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS DATES: 1/06, 7/04, 9/04</u> . |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-19, 21-39, 41-42, 44-45, 47-52, drawn to a process, classified in class 428.²⁶⁴
 - II. Claims 20, 40, 43, 46, 53, drawn to a product, classified in class 428.
2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the claimed product can be made by materially different processes such as sol-gel, the plate process, and the dip process.
3. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.
4. Claims 1-53 are generic to the following disclosed patentably distinct species groups comprising the various materials describing the: hydrocolloid, plasticizer, second film former, and bulking agent. The election of an ultimate species for each of the aforementioned groups is requested. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable

Art Unit: 1711

generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. During a telephone conversation with Liza Hohenschutz on February 10, 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-19, 21-39, 41-42, 44-45, 47-52, and the election of carrageenan as the hydrocolloid, glycerin as the plasticizer, starch derivative as the second film former, and starch hydrozylates as the bulking agent. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20, 40, 43, 46, 53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 4-~~8~~ and 24-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims that the molten composition of claims 1 and 21 are partially solids. Firstly, applicant states (in claims 1 and 21) that the molten composition is a "homogenous molten composition," then applicant states (in claims 4-9 and 24-28) that the molten composition is partially solids. It is unclear to one of ordinary skill whether the molten composition is homogenous, i.e.

Art Unit: 1711

having a uniform liquefied composition, or if the molten composition is mixed liquid and solid states.

Claim Objections

9. Claims 14, 18-20, and 38-46 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). For example, in claim 14, “any of,” should be replaced with “any one of.” Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 rejected under 35 U.S.C. 102(b) as being anticipated by Gennadios (US 6,214,376).

12. In reference to claims 1 and 3, Gennadios discloses a method for preparing thermoreversible gel films or capsules, the method comprising: heating, hydrating via the addition of an aqueous solution, stirring, and dissolving a film forming composition, wherein the process steps are completed in an apparatus. Once the composition is heated, it “thins out” and is converted from a viscous mass (dough-like) into a clear, free flowing liquid (i.e. molten), resulting in the formation of a molten composition. Gennadios does not expressly disclose that the molten composition is homogenous, however, it is inherent that since the composition is a free flowing liquid, it does not contain a solid state. Additionally, since the desired composition is formed, it is inherent that a sufficient amount of shear, temperature and residence time was provided. Solubilizing temperature,

Art Unit: 1711

as per applicants' specification (see page 6, lines 11-14), is the temperature at which the composition becomes homogenous; therefore, since the desired homogenous molten composition is formed, it is inherent that the temperature utilized was at or above the solubilizing temperature of the composition. The composition is mixed in an apparatus, which is also referred to as a fluid mixing apparatus.

13. The homogenous molten composition is then transferred or introduced for processing into a conventional gelatin encapsulation machine, the composition is initially extruded in to a film. Wherein Gennadios would envisage utilization of an extruder capable of mixing the composition.

14. Subsequently, the extruded homogenous molten composition is gelled via cooling, resulting in the formation of gel films. Wherein it is inherent that in order for the composition to gel, the temperature must be at or below its gelling temperature.

15. Note, in reference to claim 47, it is held that the term comprising is inclusive and fails to exclude unrecited steps. *In re Horvitz*, 168 F 2d 522, 78 USPQ 79 (CCPA 1948).

16. In reference to claims 2, 15 and 16, the film forming composition comprises a hydrocolloid film former such as kappa-carrageenan, a plasticizer such as glycerin, a second film former such as malodextrin (a starch derivative), and a bulking agent such as malodextrin (a starch hydrolzylate). The pH control agent is optionally claimed, hence it is not a required component of the film forming composition.

17. In reference to claim 51-52, the film forming composition of Gennadios contains a hydrocolloid film former such as kappa-carrageenan and a plasticizer, such as solid corn syrup; however, solid corn syrup is multifunctional and can also be utilized as a bulking agent. Hence a composition comprising kappa-carrageenan and solid corn syrup is considered to contain a hydrocolloid film former and a bulking agent.

Art Unit: 1711

18. In reference to claims 9-13, since the patentees gel film is the same as the applicants, it is inherent that the patentees gel film has a break force strength of at least 6,000 grams. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, since the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

19. In reference to claims 21 and 23, Gennadios discloses a method for preparing thermoreversible gel films or capsules, the method comprising: heating, hydrating via the addition of an aqueous solution, stirring, and dissolving a film forming composition, wherein the process steps are completed in an apparatus. Once the composition is heated, it "thins out" and is converted from a viscous mass (dough-like) into a clear, free flowing liquid (i.e. molten), resulting in the formation of a molten composition. Gennadios does not expressly disclose that the molten composition is homogenous, however, it is inherent that since the composition is a free flowing liquid, it does not contain a solid state. Additionally, since the desired composition is formed, it is inherent that a sufficient amount of shear, temperature and residence time was provided. Solubilizing temperature, as per applicants' specification (see page 6, lines 11-14), is the temperature at which the composition becomes homogenous; therefore, since the desired homogenous molten composition is formed, it is inherent that the temperature utilized was at or above the solubilizing temperature of the composition. The composition is mixed in an apparatus, it is also referred to as a fluid mixing apparatus.

20. The homogenous molten composition is then transferred or introduced for processing into a conventional gelatin encapsulation machine, wherein the composition is initially extruded in to a

Art Unit: 1711

film. Wherein Gennadios would envisage utilization of an extruder capable of mixing the composition.

21. Subsequently, the extruded homogenous molten composition is gelled via cooling, resulting in the formation of gel films. Wherein it is inherent that in order for the composition to gel, the temperature must be at or below its gelling temperature.

22. The gel films are then fed through a series of rollers to counter-rotating dies which form, cut and fill soft capsules of various sizes.

23. Note, in reference to claim 49, it is held that the term comprising is inclusive and fails to exclude unrecited steps. *In re Horvitz*, 168 F 2d 522, 78 USPQ 79 (CCPA 1948).

24. In reference to claims 22, 35 and 36, the film forming composition comprises a hydrocolloid film former such as kappa-carrageenan, a plasticizer such as glycerin, a second film former such as malodextrin (a starch derivative), and a bulking agent such as malodextrin (a starch hydrolzylate). The pH control agent is optionally claimed, hence it is not a required component of the film forming composition.

25. In reference to claims 29-33, since the patentees gel film is the same as the applicants, it is inherent that the patentees gel film has a break force strength of at least 6,000 grams. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, since the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

26. In reference to claims 22, 35 and 36, the film forming composition comprises a hydrocolloid film former such as kappa-carrageenan, a plasticizer such as glycerin, a second film former such as malodextrin (a starch derivative), and a bulking agent such as malodextrin (a starch hydrolzylate).

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

29. Claims 17 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gennadios (US 6,214,376) as applied to claim 1 and 21, respectively, above.

30. Gennadios discloses that the solubilizing temperature is above 130°F to below the boiling point of the working mixture (homogenous molten composition). However, Gennadios fails to disclose that the homogenous molten composition is heated, hydrated, mixed and solubilized at above atmospheric pressure. It would have been obvious to one of ordinary skill at the time of the invention to increase the pressure (to above atmospheric pressure) during the formation of the homogenous molten composition in order to decrease the time required to form the desired composition. Additionally, it would have been obvious, since the amount of pressure applied to the composition during the formation is manipulatable by an artesian, and it has been held that where

Art Unit: 1711

the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

31. Claims 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gennadios (US 6,214,376) as applied to claim 47 and 49, respectively, above, and further in view of Thanoo (US 5945126)

32. Gennadios discloses the claimed invention except for utilization of a Ross mixer as the apparatus. Hence attention is directed towards the reference. Thanoo teaches that non-static mixers, such as Ross mixers, are advantageous because one can control the mixing intensity independently of the flow rates of the feed streams into the device (12:13-40). Gennadios and Thanoo are analogous art because they are from the same field of endeavor, formation of pharmaceutical compositions.

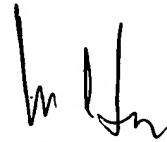
33. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to utilize a Ross Mixer as the apparatus in process of Gennadios, as taught by Thanoo, in order to control the mixing intensity independently of the flow rates of the feed streams.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saira Raza whose telephone number is (571) 272-3553. The examiner can normally be reached on Monday-Friday from 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1711

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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